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EXAMINER	
CHNG, JOY P	
ART UNIT	PAPER NUMBER
3626	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,114	YURKO ET AL.	
	Examiner	Art Unit	
	JOY CHNG	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 27-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 27-66* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. In the amendment filed 06/22/2009, the following occurred: Claims 1-4, 9, 15, 27-28, 30-31, 36-38, 40-41 and 61-62 were amended. Claim 25-26 was canceled. Therefore, claims 1-24 and 27-66 are currently pending and have been examined.

Response To Amendments

2. Applicant's arguments are persuasive and sufficient to overcome the objections to the specification with regard to trademarks set forth in the previous office action.

3. Applicant's amendments to claim 15 are sufficient to overcome the 35 U.S.C. 112 second paragraph rejections set forth in the previous office action.

4. Applicant's arguments for claims 42-66 are persuasive and sufficient to overcome the 35 U.S.C. 112 second paragraph rejections set forth in the previous office action.

5. Applicant's amendments to claim 37 are sufficient to overcome the 35 USC 101 rejections set forth in the previous office action.

6. Applicant's amendments to claims 36 and 40-41 are not sufficient to overcome the 35 USC 101 rejections set forth in the previous office action.

Claim Objections

7. Claim 4 is objected to because of the following minor informalities: grammatical error. Claim 4 recites: "(f) obtaining, at the computing device, a measurement cycle compliance value to the computing device." Appropriate correction is required.

Claim Rejections – 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 recites "...if, for a given compliance period, the sum of the weighted measurements for the usage sessions that occurred during the given compliance period is greater than or equal to the compliance value". It is unclear if any of these steps happen as they are not positively recited. All claims dependent from these claims are rejected for the same reasons.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 36 and 40-41 are rejected under 35 U.S.C. 101. Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In re Bilski et al, 88 USPQ 2d 1385 CAFC (2008); Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876).

13. To qualify as a § 101 statutory process, the claim should recite the particular machine or apparatus to which it is tied, for example by identifying the machine or apparatus that accomplishes the method steps, or positively reciting the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

14. There are two corollaries to the machine-or-transformation test. First, a mere field-of-use limitation is generally insufficient to render an otherwise ineligible method claim patent-eligible. This means the machine or transformation must impose meaningful limits on the method claim's scope to pass the test.

15. Second, insignificant extra-solution activity will not transform an unpatentable principle into a patentable process. This means reciting a specific machine or a particular transformation of a specific article in an insignificant step, such as data gathering or outputting, is not sufficient to pass the test.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 42-43 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Remes et al. (US Patent 5,706,801).

Claim 42:

Remes, as shown, discloses the following limitations:

- *(a) a medical device adapted to provide a treatment to a patient* (see at least Col. 1, lines 23-25);
- *(b) means for monitoring an actual medical device usage* (see at least Col. 3, lines 62-65);
- *(c) processing means for determining a compliance period value as a number of compliance periods in a measurement cycle in which the actual medical device usage value is at least equal to a minimum medical device usage compliance value* (reads on "allowed variation")(see at least Col. 6, lines 9-11, lines 29-38).

Claim 43:

Remes discloses the limitations shown in the rejections above. Remes further discloses the following limitations:

- *wherein the processing means compares the compliance period value with a medical device usage prescription value* (see at least Col. 6, lines 9-11, lines 34-38).

Claim 53:

Remes discloses the limitations shown in the rejections above. Remes further discloses the following limitations:

- *(e) a communication device associated with the medical device* (see at least Col. 1, lines 16-19; Col. 2, lines 46-50);
- *(f) a central database remote from the medical device and in communication therewith via the communication device* (see at least Abstract, lines 8-10; Col. 2, lines 59-62; Col.5, lines 11-13, lines 44-47).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 1-6, 9, 10-18 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler and further in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al.

Claim 1:

Nicholson, as shown, discloses the following limitations:

- *(a) obtaining via a computing device a minimum medical device usage compliance value* (reads on "dose size") *for a medical device for a predetermined compliance period* (reads on "per day")(see at least Col. 7, lines 37-38; Col. 10, lines 44-46)*;*
- *(b) obtaining via the computing device a quantity of the compliance periods* (reads on "30") *in a measurement cycle* (see at least Col. 13, lines 52-58)*;*
- *(c) obtaining via the computing device measurements of actual medical device usage of the medical device during the measurement cycle* (see at least Col. 8, lines 37-41)*;*

Nicholson does not specifically disclose the following limitations, but Kaigler as shown does:

- *(d) weighting, via the computing device, the measurements of medical device usage for individual usage sessions during the measurement cycle according to a predetermined weighting scheme* (see at least Paragraph 49, lines 5-11)*;*
- *wherein the weighted measurements of medical device usage indicate actual medical device usage has satisfied the compliance value if, for a given compliance period, the*

sum of the weighted measurements for the usage sessions that occurred during the given compliance period is greater than or equal to the compliance value (see at least Paragraph 49).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson with the weighting of Kaigler because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Nicholson does not specifically disclose the following limitation, but Kribbs, as shown does:

- *(e) determining, via the computing device, whether a compliance period value for the measurement cycle, as the number of compliance periods in the measurement cycle for which the weighted measurements of medical device usage indicate that the actual medical device usage has satisfied the compliance value, is at least equal to the minimum medical device usage compliance value* (reads on "4-hour use")(see at least Fig. 3; Page 890, Col. 2, lines 8-11).

Kribbs does not specifically disclose *computing device,* but Nicholson in at least Col. 8, lines 59-63, as shown does.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the weighting of Kaigler with the minimum usage of Kribbs because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 2:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *(f) obtaining, at the computing device, a medical device usage prescription value* (reads on "doses per day") (see at least Col. 10, lines 44-46);

- *(g) comparing* (reads on "computes"), *via the computing device, the compliance period value with the medical device usage prescription value* (see at least Col. 8, lines 59-63).

Claim 3:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson does not specifically disclose the following limitation, but Kaigler, as shows does:

- *wherein the compliance period value is determined as a percentage of compliance periods in the measurement cycle in which the weighted measurements of medical device usage indicate actual medical device usage has satisfied the compliance value* (see at least Paragraph 49).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the minimum usage of Kribbs with the percentage of Kaigler because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 4:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *(h) providing a compliance indicator* (reads on "score") *from the computing device based upon results of the comparison* (see at least Col. 1, lines 17-19).

Nicholson does not specifically disclose the following limitation, but Kaigler, as shown does:

- *(f) obtaining, at the computing device, a measurement cycle compliance value to the computing device* (see at least Paragraph 48, lines 16-18);

Nicholson does not specifically disclose the following limitation, but Kribbs, as shown does:

- *(g) comparing, in the computing device, the compliance period value with the measurement cycle compliance value* (see at least Page 889, Col. 2, lines 3-4);

Kribbs does not specifically disclose *computing device,* but Nicholson in at least Col. 8, lines 59-63, as shown does.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the value of Kaigler with the minimum usage of Kribbs because it "...can then be used to evaluate patient compliance with the programmed treatment plan..." (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 5:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *(1) a compliance signal responsive to the compliance period value being at least equal to the measurement cycle compliance value* (see at least Fig. 5, Ele. 48C; Col. 1, lines 17-19; Col. 5, lines 2-4),
- *(2) a non-compliance signal responsive to the compliance period value being less than the measurement cycle compliance value* (see at least Col. 6, lines 51-55).

Nicholson does not specifically disclose *measurement cycle compliance value* (reads on "4 h"), but Kribbs in at least Page 889, Col. 2, lines 18-20 and Page 890, Col. 1, lines 18-20.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the value of Kaigler with the measurement cycle compliance value of Kribbs because it "...can then be used to evaluate patient compliance with the programmed treatment plan..." (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 6:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the compliance indicator indicates a compliance value signal* (reads on "compliance score")(see at least Fig. 5, Ele. 48C; Col. 1, lines 17-19; Col. 5, lines 2-4).

Claim 9:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *(f) obtaining, at the computing device, a compliance warning value* (reads on "time value") (see at least Col. 6, lines 29-31);
- *(g) comparing, in the computing device, the compliance period value with the compliance warning value* (see at least Col. 6, lines 33-37);
- *(h) generating, by the computing device, a warning signal* (reads on "flash") *responsive to the comparison of the compliance period value with the compliance warning value* (see at least Col. 6, lines 51-55).

Claim 10:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson and Kribbs do not specifically disclose the following limitations, but Kaigler, as shown does:

- *wherein the compliance warning value is set by a user* (see at least Paragraph 34; Paragraph 48, lines 16-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the minimum usage of Kribbs with the value of Kaigler because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 11:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the warning signal is an audible alarm, a visual display, or both* (see at least Col. 6, lines 51-55).

Claim 12:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the warning signal is a visual display and includes an alphanumeric message* (see at least Col. 6, lines 51-55).

Claim 13:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the alphanumeric message* (reads on "display parameters") *is user-defined* (reads on "programmed")(see at least Col. 6, lines 48-49).

Claim 14:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the compliance period is a 24-hour period* (see at least Col. 10, lines 44-46).

Claim 15:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the compliance period is a fixed period of time, a rotating period of time, or a dynamic period of time* (see at least Col. 10, lines 44-46).

Claim 16:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the measurement cycle is a monthly period* (see at least Col. 13, lines 52-58).

Claim 17:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson and Kribbs do not specifically disclose the following limitations, but Kaigler, as shown does:

- *wherein the medical device is a nebulizer* (see at least Paragraph 36, lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the minimum usage of Kribbs with the device of Kaigler

because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 18:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson and Kribbs do not specifically disclose the following limitations, but Kaigler, as shown does:

- *wherein the actual medical device usage value is based upon operation of at least one component of the medical device* (see at least Paragraph 36, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the minimum usage of Kribbs with the usage of Kaigler because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 30:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson does not specifically disclose the following limitations, but Kribbs as shown does:

- *comparing, via the computing device, the measurements of medical device usage during the usage sessions of a compliance period with the minimum medical device usage short session value* (see at least Fig. 3; Page 889, Col. 2, lines 8-11);
- *determining, via the computing device, a short session count value based upon the number of usage sessions wherein the measurement of medical device usage for the respective usage session is less than the minimum medical device usage short session value* (reads on "less than 4 h per night")(see at least Page 889, Col. 2, lines 18-20).

Nicholson does not specifically disclose the following limitations, but Kaigler as shown does:

- *obtaining, via the computing device, a minimum medical device usage short session value* (see at least Paragraph 48, lines 12-18);

Kribbs does not specifically disclose *computing device,* but Nicholson in at least Col. 8, lines 59-63, as shown does.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the value of Kaigler with the minimum usage of Kribbs because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 31:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *obtaining, via the computing device, a short session warning value* (reads on "time value") (see at least Col. 6, lines 29-31)*;*
- *comparing, in the computing device, the short session count value with the short session warning value* (see at least Col. 6, lines 33-37)*;*
- *generating, via the computing device, a warning signal* (reads on "flash") *responsive to the short session count value being equal to the short session warning value* (see at least Col. 6, lines 51-55).

Claim 32:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson and Kribbs do not specifically disclose the following limitations, but Kaigler as shown does:

- *wherein the short session warning value is set by a user* (see at least Paragraph 34; Paragraph 36, lines 8-11; Paragraph 48, lines 16-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the minimum usage of Kribbs with the value of Kaigler because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 33:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the warning sign*(see at least Col. 6, lines 51-55).*al is at least one of an audible alarm and a visual display* (see at least Col. 6, lines 51-55).

Claim 34:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the warning signal is a visual display and includes an alphanumeric message* (see at least Col. 6, lines 51-55).

Claim 35:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *wherein the alphanumeric message* (reads on "display parameters") *is user-defined* (reads on "programmed")(see at least Col. 6, lines 48-49).

Claim 36:

Nicholson, as shown, discloses the following limitations.

- *(b) receiving, via the computing device, measurements of medical device usage for at least one discrete medical device usage session* (see at least Col. 8, lines 28-31, lines 37-39)*;*

Nicholson does not specifically disclose the following limitations, but Kaigler as shown does:

- *(a) receiving, via a computing device, a minimum medical device usage short session value* (see at least Paragraph 49, lines 1-5)*;*
- *(d) determining a medical device usage value for the compliance period by summing the measurements of medical device usage for each medical device usage session that is greater than or equal to the minimum medical device usage short session value and excluding from the sum each measurement of medical device usage during a medical*

device usage session during the compliance period that is less than the minimum medical device usage short session value (see at least Paragraph 36, lines 8-14).

Nicholson does not specifically disclose the following limitations, but Kribbs as shown does:

- *(c) comparing the measurement of medical device usage for each medical device usage session with the minimum medical device usage short session value* (see at least Fig. 3; Page 889, Col. 2, lines 8-11);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson and the value of Kaigler with the minimum usage of Kribbs because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

20. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler.

Claim 40:

Nicholson, as shown, discloses the following limitations:

- *(b) obtaining, via the computing device, a measurement of medical device usage for at least one discrete medical device usage session* (see at least Col. 8, lines 28-31, lines 37-39);

Nicholson does not specifically disclose the following limitations, but Kaigler as shown does:

- *(a) obtaining, via a computing device, a minimum medical device usage short session value* (see at least Paragraph 49, lines 1-5);
- *(c) comparing, via the computing device, the measurements of medical device usage for individual ones of the at least one discrete usage session with the minimum medical device usage short session value* (see at least Paragraph 36, lines 8-14);

(d) determining a short session count value based upon the number of usage sessions wherein the measurement of medical device usage for the respective usage session is less than the minimum medical device usage short session value (see at least Paragraph 36, lines 8-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson with the minimum usage of Kaigler because it "...can then be used to evaluate patient compliance with the programmed treatment plan..." (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 41:

The combination of Nicholson/Kaigler discloses the limitations shown in the rejections above. Nicholson further discloses the following limitations:

- *(e) obtaining, via a computing device, a short session warning value* (reads on "time value") (see at least Col. 6, lines 29-31);
- *(f) comparing, in the computing device, the short session count value with the short session warning value* (see at least Col. 6, lines 33-37);
- *(g) generating, by the computing device, a warning signal* (reads on "flash") *responsive to the short session count value being equal to the short session warning value* (see at least Col. 6, lines 51-55).

21. Claims 7-8 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al. and further in view of U.S. Patent 5,706,801 to Remes et al.

Claim 7:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Remes, as shown does:

- *(i) creating a report based upon the compliance indicator and indicative of at least one patient's compliance with a medical device usage prescription value* (see at least Fig. 7; Col. 6, lines 35-38).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson, the weighting of Kaigler and the minimum usage of Kribbs with the report of Remes because "...it can be determined whether the patient is or is not in compliance for each reporting period..." (Remes, see at least Col. 6, lines 36-38).

Claim 8:

The combination of Nicholson/Kaigler/Kribbs/Remes discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Remes, as shown does:

- *wherein the report is in the form of a graph* (see at least Fig. 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson, the weighting of Kaigler and the minimum usage of Kribbs with the report of Remes because "...it can be determined whether the patient is or is not in compliance for each reporting period..." (Remes, see at least Col. 6, lines 36-38).

Claim 22:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Remes, as shown does:

- *wherein at least a flow rate is communicated between the medical device and a remote computing system by a direct link* (reads on "phone line")(see at least Col. 2, lines 59-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson, the weighting of Kaigler and the minimum usage of Kribbs with the communication of Remes because "the information collected is, preferably, stored and periodically transmitted via a communication module" (Remes, see at least Col. 2, lines 5-7).

Claim 23:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Remes, as shown does:

- *wherein at least a flow rate is stored as data fields on a central database* (see at least Col. 2, lines 59-62; Col.5, lines 11-13, lines 44-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson, the weighting of Keigler and the minimum usage of Kribbs with the database of Remes because it provides a "means, at said remote location, for storing information specifying a prescribed regimen of use for said patient including session length and delivered flow rate information, for receiving transmitted data and comparing it to the prescribed session length and delivered flow rate information to determine patient and oxygen delivery apparatus compliance with the prescribed regimen of use" (Remes, see at least Col. 6, lines 60-66).

Claim 24:

The combination of Nicholson/Kaigler/Kribbs/Remes discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Remes, as shown does:

- *wherein the central database is resident on one of a computing system, a home care provider network, a primary care provider network, an insurance network and a manufacturer network* (see at least Abstract, lines 8-10; Col. 2, lines 59-62; Col.5, lines 11-13, lines 44-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson and the minimum usage of Kribbs with the database of Remes because it provides a "means, at said remote location, for storing information specifying a prescribed regimen of use for said patient including session length and delivered flow rate information, for receiving transmitted data and comparing it to the prescribed session length

and delivered flow rate information to determine patient and oxygen delivery apparatus compliance with the prescribed regimen of use" (Remes, see at least Col. 6, lines 60-66).

22. Claims 45-48, 60 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al. and further in view of U.S. Patent 5,706,801 to Remes et al.

Claim 45:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitation, but Kribbs, as shown does:

- *wherein the processing means compares the compliance period value with a measurement cycle compliance value* (see at least Page 889, Col. 2, lines 3-4),

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the minimum usage of Kribbs because it enables "…periodic reporting of apparatus performance and information regarding patient compliance with a prescribed regimen of use" (Remes, see at least Col. 1, lines 10-12).

Remes and Kribbs do not specifically disclose the following limitation, but Nicholson, as shown does:

- *further comprising means for outputting a compliance indicator* (reads on "score") *based upon results of the comparison* (see at least Col. 1, lines 17-19).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the minimum usage of Kribbs with the indicator of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 46:

The combination of Remes/Kribbs/Nicholson discloses the limitations shown in the rejections above. Remes and Kribbs do not specifically disclose the following limitation, but Nicholson, as shown does:

- *(1) a compliance signal responsive to the compliance period value being at least equal to the measurement cycle compliance value* (see at least Fig. 5, Ele. 48C; Col. 1, lines 17-19; Col. 5, lines 2-4),
- *(2) a non-compliance signal responsive to the compliance period value being less than the measurement cycle compliance value* (see at least Col. 6, lines 51-55)..

Nicholson does not specifically disclose *measurement cycle compliance value* (reads on "4 h"), but Kribbs in at least Page 889, Col. 2, lines 18-20 and Page 890, Col. 1, lines 18-20.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the minimum usage of Kribbs with the indicator of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 47:

The combination of Remes/Kribbs/Nicholson discloses the limitations shown in the rejections above. Remes and Kribbs do not specifically disclose the following limitations, but Nicholson as shown does:

- *wherein the compliance indicator indicates a compliance value signal* (reads on "compliance score")(see at least Fig. 5, Ele. 48C; Col. 1, lines 17-19; Col. 5, lines 2-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the minimum usage of Kribbs with the indicator of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 48:

The combination of Remes/Kribbs/Nicholson discloses the limitations shown in the rejections above. Remes further discloses the following limitations:

- *wherein the outputting means creates a report based upon the compliance indicator and indicative of at least one patient's compliance with at least one of a medical device usage prescription value* (see at least Fig. 7; Col. 6, lines 35-38).

Claim 60:

The combination of Remes/Kribbs discloses the limitations shown in the rejections above. Remes and Kribbs do not specifically disclose the following limitations, but Nicholson as shown does:

- *wherein the processing means compares the short session count value with a short session warning value, and further comprising an outputting means for presenting a warning signal responsive to the short session count value being equal to the short session warning value* (see at least Col. 6, lines 33-37, lines 51-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the minimum usage of Kribbs with the means of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 66:

The combination of Remes/Kribbs discloses the limitations shown in the rejections above. Remes and Kribbs do not specifically disclose the following limitations, but Nicholson as shown does:

- *wherein the processing means also compares the short session count value with a short session warning value, and further comprising and outputting means for presenting a warning signal responsive to the short session count value being equal to the short session warning value* (see at least Col. 6, lines 33-37, lines 51-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the means of Kribbs with the means of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

23. Claims 49, 51-52 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,706,801 to Remes et al. in view of U.S. Patent 6,249,717 B1 to Nicholson et al.

Claim 49:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitations, but Nicholson as shown does:

- *wherein the processing means compares the compliance period value with a compliance warning value, and further comprising outputting means for presenting a warning signal responsive to the compliance period value being equal to the compliance warning value* (see at least Col. 6, lines 33-37, lines 51-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the minimum usage of Kribbs with the indicator of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 51:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitation, but Nicholson, as shown does:

- *wherein the means for monitoring usage and the processing means are resident in the medical device* (reads on "apparatus")(see at least Col. 1, lines 16-19).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the means of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 52:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitation, but Nicholson, as shown does:

- *a communication device associated with the medical device, and wherein the means for monitoring usage is resident in the medical device and the processing means is resident*

in the communication device (see at least Col. 1, lines 16-19; Col. 2, lines 46-50, lines 59-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the minimum usage of Kribbs with the communication of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 54:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitation, but Nicholson, as shown does:

- *wherein the processing means determines the actual medical device usage value for the compliance period based upon an actual medical device session usage value determined for each of a plurality of discrete usage sessions* (see at least Col. 8, lines 28-31, lines 37-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the means of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 55:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitation, but Nicholson, as shown does:

- *wherein the processing means determines the actual medical device usage value for the compliance period as a sum of the actual medical device session usage values accruing during the compliance period* (see at least Col. 9, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the means of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

24. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al. in view of U.S. Patent 5,284,133 to Burns et al. and further in view of U.S. Patent 5,517,983 to Deighan et al.

Claim 19:

The combination of Nicholson/Kaigler/Kribbs/Burns discloses the limitations shown in the rejections above. Nicholson, Kaigler, Kribbs and Burns do not specifically disclose the following limitations, but Deighan, as shown does:

- *wherein the component is one of a blower, a battery, a power input and a motor* (see at least Col. 2, lines 59-65).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson, the weighting of Kaigler, the minimum usage of Kribbs and the medical device of Burns with the component of Deighan because it provides "...an inhalation device which can provide some assurance that a patient is not circumventing a dosing schedule by not inhaling medication" (Burns, see at least Col. 3, lines 36-38).

25. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al. and further in view of U.S. Patent 5,517,983 to Deighan et al.

Claim 20:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Deighan, as shown does:

- *wherein the actual medical device usage value is based upon a measured physical parameter* (reads on "pressure")(see at least Col. 2, lines 28-34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson and the weighting of Kaigler and the minimum usage of Kribbs with the measurement of Deighan because it determines "...whether the device has actually been used by the patient" (Deighan, see at least Col. 1, lines 34-35).

Claim 21:

The combination of Nicholson/Kaigler/Kribbs/Deighan discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Deighan, as shown does:

- *wherein the measured physical parameter is a pressure differential* (seat least Col. 2, lines 28-34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson, the weighting of Keigler and the minimum usage of Kribbs with the measurement of Deighan because it determines "...whether the device has actually been used by the patient" (Deighan, see at least Col. 1, lines 34-35).

26. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al. and further in view of U.S. Patent 6,578,003 B1 to Camarda et al.

Claim 27:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Camarda as shown does:

- *determining, within the computing device, weighting factors for individual usage sessions during the measurement cycle according to the predetermined weighting scheme* (see at least Col. 12, lines 43-47);

- *applying, within the computing device, the weighting factors to measurements of medical device usage for the corresponding usage sessions* (reads on "the variable")(see at least Col. 12, lines 43-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson, the weighting of Kaigler and the minimum usage of Kribbs with the weighting of Camarda because "...it allows a score to be assigned to each record" (Camarda, see at least Abstract, lines 20-21).

Claim 28:

The combination of Nicholson/Kaigler/Kribbs discloses the limitations shown in the rejections above. Nicholson, Kaigler and Kribbs do not specifically disclose the following limitations, but Camarda as shown does:

- *wherein the weighting factor determined for an individual usage session is variable dependent* (reads on "indicate the relative significance") *upon the measurement of medical device usage for the individual usage session* (reads on "the variable")(see at least Col. 12, lines 43-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson, the weighting of Kaigler and the minimum usage of Kribbs with the weighting of Camarda because "...it allows a score to be assigned to each record" (Camarda, see at least Abstract, lines 20-21).

27. Claim 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al. in view of U.S. Patent 6,578,003 B1 to Camarda et al. and further in view of U.S. Patent 5,359,513 to Kano et al.

Claim 29:

The combination of Nicholson/Kaigler/Kribbs/Camarda discloses the limitations shown in the rejections above. Nicholson, Kaigler, Kribbs and Camarda do not specifically disclose the following limitations, but Kano as shown does:

- *wherein the weighting factor is in a range from 0 to 1* (see at least Fig. 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson, the weighting of Kaigler, the minimum usage of Kribbs and the weighting of Camarda with the range of Kano because it represents "...the relative significance of the variable..." (Camarda, see at least Col. 3, lines 33-35).

28. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler.

Claim 37:

Nicholson, as shown, discloses the following limitations:

- *(a) obtaining, via a computing device, measurements of actual medical device usage for each discrete medical device usage session* (see at least Col. 8, lines 28-31, lines 37-39);

Nicholson does not specifically disclose the following limitations, but Kaigler as shown does:

- *(b) applying, via the computing device, a weighting factor to the measurements of actual device usage during each of the usage sessions to produce a weighted actual medical device session usage value for each medical device usage session* (reads on "the variable")(see at least Paragraph 49);
- *(c) determining, via the computing device, an actual medical device usage value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period* (see at least Paragraph 36, lines 8-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson with the value of Kaigler because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 38:

The combination of Nicholson/Kaigler discloses the limitations shown in the rejections above. Nicholson and Kaigler do not specifically disclose the following limitations, but Camarda as shown does:

- *wherein the weighting factor for a particular usage session is variable dependent* (reads on "indicate the relative significance") *upon the measurement of medical device usage during the particular usage session* (see at least Col. 12, lines 43-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the computing device of Nicholson and the value of Kaigler with the weighting of Camarda because "…it allows a score to be assigned to each record" (Camarda, see at least Abstract, lines 20-21).

29. Claim 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,249,717 B1 to Nicholson et al. in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler in view of U.S. Patent 6,578,003 B1 to Camarda et al. and further in view of U.S. Patent 5,359,513 to Kano et al.

Claim 39:

The combination of Nicholson/Kaigler/Camarda discloses the limitations shown in the rejections above. Nicholson, Kaigler and Camarda do not specifically disclose the following limitations, but Kano as shown does:

- *wherein the weighting factor is in a range from 0 to 1* (see at least Fig. 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Nicholson, the value of Kaigler and the weighting of Camarda with the

range of Kano because it represents "…the relative significance of the variable…" (Camarda, see at least Col. 3, lines 33-35).

30. Claims 44, 59 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,706,801 to Remes et al. in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al.

Claim 44:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitation, but Kribbs, as shown does:

- *wherein the processing means determines the compliance period value as a percentage of compliance periods in the measurement cycle in which the actual medical device usage value is at least equal to the minimum medical device usage compliance value* (see at least Page 890, Col. 1, lines 18-20).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the minimum usage of Kribbs because it enables "…periodic reporting of apparatus performance and information regarding patient compliance with a prescribed regimen of use" (Remes, see at least Col. 1, lines 10-12).

Claim 59:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitations, but Kribbs as shown does:

- *wherein the input means is used to provide a minimum medical device usage short session value to the processing means* (see at least Page 889, Col. 2, lines 8-11), *wherein the processing means*
  - *(1) compares the actual medical device usage value for a discrete usage session with the minimum medical device usage short session value* (see at least Fig. 3; Page 889, Col. 2, lines 8-11);
  - *(2) determines a short session count value based upon the number of usage sessions wherein the actual medical device usage value for the respective usage*

session is less than the minimum medical device usage short session value

(reads on "less than 4 h per night")(see at least Page 889, Col. 2, lines 18-20).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the minimum usage of Kribbs because it enables "…periodic reporting of apparatus performance and information regarding patient compliance with a prescribed regimen of use" (Remes, see at least Col. 1, lines 10-12).

Claim 65:

Remes, as shown, discloses the following limitations:

- *(a) a medical device adapted to provide a treatment to a patient* (see at least Col. 1, lines 23-25);
- *(b) means for monitoring an actual medical device usage for at least one discrete medical device usage session* (see at least Col. 3, lines 62-65);

Remes does not specifically disclose the following limitations, but Kribbs as shown does:

- *(c) processing means for:*
  - *(1) comparing the actual medical device usage value for a discrete usage session with a minimum medical device usage short session value* (see at least Fig. 3; Page 889, Col. 2, lines 8-11),
  - *(2) determining a short session count value based upon the number of usage sessions where the actual medical device usage value for the respective usage session is less than the minimum medical device usage short session value*

(reads on "less than 4 h per night")(see at least Page 889, Col. 2, lines 18-20).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the means of Kribbs because it enables "…periodic reporting of apparatus performance and information regarding patient compliance with a prescribed regimen of use" (Remes, see at least Col. 1, lines 10-12).

31. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,706,801 to Remes et al. in view of *Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea* to Kribbs et al. and further in view of U.S. Patent Application Publication US 2003/0221687 A1 to Kaigler.

Claim 61:

Remes, as shown, discloses the following limitations:

- *(a) a medical device adapted to provide a treatment to a patient* (see at least Col. 1, lines 23-25)*;*
- *(b) means for monitoring an actual medical device usage for at least one discrete medical device usage session during a compliance period* (see at least Col. 3, lines 62-65)*;*

Remes does not specifically disclose the following limitations, but Kribbs as shown does:

- *(c) processing means for*
  - *(1) comparing the actual medical device usage value for each medical device usage session with the minimum medical device usage short session value* (see at least Fig. 3; Page 889, Col. 2, lines 8-11)*;*

Remes and Kribbs do not specifically disclose the following limitations, but Kaigler as shown does:

- *(2) determining an actual medical device usage value for the compliance period by summing the actual medical device usage value for each medical device usage session during the compliance period that is greater than or equal to the minimum medical device usage short session value and excluding from the sum the actual medical device usage values for medical device usage sessions during the compliance period that are less than the minimum medical device usage short session value* (see at least Paragraph 36, lines 8-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the minimum usage of Kribbs with the value of Kaigler

because it enables "…periodic reporting of apparatus performance and information regarding patient compliance with a prescribed regimen of use" (Remes, see at least Col. 1, lines 10-12).

32. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,706,801 to Remes et al. in view of U.S. Patent 5,284,133 to Burns et al.

Claim 50:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitation, but Burns, as shown does:

- *wherein the medical device is a nebulizer* (see at least Col. 1, lines 17-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to the medical device of Remes with the medical device of Burns because it provides "…an inhalation device which can provide some assurance that a patient is not circumventing a dosing schedule by not inhaling medication" (Burns, see at least Col. 3, lines 36-38).

33. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,706,801 to Remes et al. in view of U.S. Patent 6,578,003 B1 to Camarda et al.

Claim 56:

Remes discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitations, but Camarda as shown does:

- *wherein the processing means applies a weighting factor to at least one actual medical device session usage value* (see at least Col. 12, lines 43-47);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the weighting of Camarda because "…it allows a score to be assigned to each record" (Camarda, see at least Abstract, lines 20-21).

Claim 57:

The combination of Remes/Camarda discloses the limitations shown in the rejections above. Remes does not specifically disclose the following limitations, but Camarda as shown does:

- *wherein the weighting factor is variable dependent* (reads on "indicate the relative significance") *upon the actual medical device session usage value* (reads on "the variable")(see at least Col. 12, lines 43-47)..

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the weighting of Camarda because "...it allows a score to be assigned to each record" (Camarda, see at least Abstract, lines 20-21).

34. Claim 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,706,801 to Remes et al. in view of U.S. Patent 6,578,003 B1 to Camarda et al. and further in view of U.S. Patent 5,359,513 to Kano et al.

Claim 58:

The combination of Remes/Camarda discloses the limitations shown in the rejections above. Remes and Camarda do not specifically disclose the following limitations, but Kano as shown does:

- *wherein the weighting factor is in a range from 0 to 1* (see at least Fig. 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the weighting of Camarda with the range of Kano because it represents "...the relative significance of the variable..." (Camarda, see at least Col. 3, lines 33-35).

35. Claims 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,706,801 to Remes et al. in view of in view of U.S. Patent 6,578,003 B1 to Camarda et al. and further in view of U.S. Patent 6,249,717 B1 to Nicholson et al.

Claim 62:

Remes, as shown, discloses the following limitations:

- *(a) a medical device adapted to provide a treatment to a patient* (see at least Col. 1, lines 23-25);
- *(b) means for monitoring an actual medical device usage for at least one discrete medical device usage session* (see at least Col. 3, lines 62-65);

Remes does not specifically disclose the following limitations, but Camarda as shown does:

- *(c) processing means for*
  - *(1) applying a weighting factor to each actual medical device session usage value to produce a weighted actual medical device session usage value for each medical device usage session* (reads on "the variable")(see at least Col. 12, lines 43-47);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes with the weighting of Camarda because "…it allows a score to be assigned to each record" (Camarda, see at least Abstract, lines 20-21).

Remes and Camarda do not specifically show the following limitations, but Nicholson as shown does:

- *(2) determining an actual medical device usage value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period* (see at least Col. 9, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the weighting of Camarda with the determination of Nicholson because it "…can then be used to evaluate patient compliance with the programmed treatment plan…" (Nicholson, see at least Col. 1, line 67 through Col. 2, line 1).

Claim 63:

The combination of Remes/Camarda/Nicholson discloses the limitations shown in the rejections above. Remes and Nicholson do not specifically disclose the following limitations, but Camarda as shown does:

- *wherein the weighting factor is variable dependent* (reads on "indicate the relative significance") *upon the actual medical device session usage value* (reads on "the variable")(see at least Col. 12, lines 43-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes and the determination of Nicholson with the weighting of Camarda because "...it allows a score to be assigned to each record" (Camarda, see at least Abstract, lines 20-21).

36. Claim 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,706,801 to Remes et al. in view of U.S. Patent 6,578,003 B1 to Camarda et al. in view of U.S. Patent 6,249,717 B1 to Nicholson et al. and further in view of U.S. Patent 5,359,513 to Kano et al.

Claim 64:

The combination of Remes/Camarda/Nicholson discloses the limitations shown in the rejections above. Remes, Camarda and Nicholson do not specifically disclose the following limitations, but Kano as shown does:

- *wherein the weighting factor is in a range from 0 to 1* (see at least Fig. 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the medical device of Remes, the weighting of Camarda and the determination of Nicholson with the range of Kano because it represents "...the relative significance of the variable..." (Camarda, see at least Col. 3, lines 33-35).

Response To Arguments

37. Applicant's arguments from the response filed on 06/22/2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appeared.

38. In the remarks, Applicant asserts that (1) there is no disclosure in the '801 patent (Remes et al.) that allowed variations are relevant to "determining...a number of compliance periods in a measurement cycle in which the actual medical device usage value is at least equal to a minimum medical device usage compliance value"; (2) the '717 patent (Nicholson et al.) and Kribbs, alone or in combination, do not teach or suggest the weighting of measurements of therapy that has been administered to a patient; (3) there is no teaching of "determining a medical device usage value for the compliance period by summing"; (4) the Examiner has failed to demonstrate that the cited references teach or suggest adjusting a quantification of past compliance for this effect in the manner recited in claim 37; and that (5) there is no teaching of "determining a short session count value based upon the number of "blank areas".

39. In response to applicant's arguments (1) as listed above, the examiner respectfully disagrees. The Examiner respectfully submits that the '801 patent (Remes et al.) teaches the processing means comprising a database program that applies a predetermined set of criteria to the data to allow the data to be grouped and reported (see at least Col. 5, lines 36-39). In addition, the '801 patent teaches a graph permitting patient compliance to be determined. Further, the '801 patent teaches that it can be determined with the patient's actual use, whether the patient is or is not in compliance for each reporting period.

40. In response to applicant's arguments (2), (3) (4) and (5) as listed above, the examiner respectfully disagrees. Applicant's amendments necessitated new grounds of rejections and have been addressed above. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

41. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

42. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

43. Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Joy Chng** whose telephone number is **571.270.7897**. The Examiner can normally be reached on Monday-Friday, 9:00am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **CHRISTOPHER L. GILLIGAN** can be reached at **571.272.6770**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington, D.C. 20231

or faxed to **571-273-8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

Randolph Building

401 Dulany Street

Alexandria, VA 22314.

/Joy Chng/

6 November 2009

Examiner, Art Unit 3626

/C. Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626